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PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 4869bis.WO	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/FR99/02269	International filing date (*day/month/year*) 23 September 1999 (23.09.99)	Priority date (*day/month/year*) 23 September 1998 (23.09.98)
International Patent Classification (IPC) or national classification and IPC G01N 33/487		
Applicant DIGIBIO		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 8 sheets, including this cover sheet.

☒ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 7 sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☐ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☒ Certain defects in the international application
- VIII ☒ Certain observations on the international application

Date of submission of the demand 14 April 2000 (14.04.00)	Date of completion of this report 29 December 2000 (29.12.2000)
Name and mailing address of the IPEA/EP Facsimile No.	Authorized officer Telephone No.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/FR99/02269

I. Basis of the report

1. With regard to the **elements** of the international application:*

☐ the international application as originally filed

☒ the description:

pages 1-26, as originally filed

pages _____, filed with the demand

pages _____, filed with the letter of _____

☒ the claims:

pages _____, as originally filed

pages _____, as amended (together with any statement under Article 19

pages _____, filed with the demand

pages 1-26, filed with the letter of 17 November 2000 (17.11.2000)

☒ the drawings:

pages 1/2, 2/2, as originally filed

pages _____, filed with the demand

pages _____, filed with the letter of _____

☐ the sequence listing part of the description:

pages _____, as originally filed

pages _____, filed with the demand

pages _____, filed with the letter of _____

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language _____ which is:

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

☐ the language of publication of the international application (under Rule 48.3(b)).

☐ the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☐ contained in the international application in written form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____

☐ the claims, Nos. _____

☐ the drawings, sheets/fig _____

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* *Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rule 70.16 and 70.17).*

** *Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.*

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☒ the entire international application.

☐ claims Nos. _____

because:

☒ the said international application, or the said claims Nos. 1-26
relate to the following subject matter which does not require an international preliminary examination *(specify)*:

See the Supplemental Box.

☒ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. 3, 7, 11, 15
are so unclear that no meaningful opinion could be formed *(specify)*:

See the Supplemental Box.

☐ the claims, or said claims Nos. _____ are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for said claims Nos. _____.

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: III

1. The "receiving substance" and the "biological system" mentioned in the claims can be a human or animal body (see application description, especially page 5, lines 21 and 22; also note that the possibility of producing heparin directly in a human or animal body is not excluded by the description), and, according to the applicant, the signals obtained in accordance with the invention and applied to said body have therapeutic qualities. It must therefore be considered that Claims 1, 2, 6 to 9, 12 to 14 and 22 to 25 define methods of treating the human or animal body. However, where this is the case, Rule PCT 67.1 (iv) authorises the international preliminary examining authority concerned not to carry out an examination of the subject matter of said claim.

2. Claims 19 to 21 have not been examined either, as the signal claimed therein is not considered to have been sufficiently defined (PCT Article 6, clarity). Indeed, it does not seem possible for a person skilled in the art to establish whether a given signal has been obtained by the method as per the invention or by another method. The claimed signal simply consists of information which does not appear to be easily reproducible, as the applicant has not proved convincingly that a source substance energised in the same way always produced the same "characteristic" signal (in the meaning of the invention, see application, page 1, line 20 to page 2, line 4).

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: III

There is also another reason for which the subject matter of these claims was not examined, which is the fact that the claimed signal may be considered to be a mere presentation of information. PCT Rule 67.1.(v) allows such subject matter to be excluded from examination (see also PCT Guidelines, PCT/GL/3, Chapter IV, point 2.4(e)).

3. Claims 3, 7, 11 and 15 are not fully supported by the description, contrary to the requirements of PCT Article 6. Indeed, these claims mention that the excitation field can be any electric, magnetic and/or electromagnetic field whatsoever, whereas the description gives only one single example of an excitation field, that is an HF electromagnetic field. There is therefore no reason to suppose that an excitation field other than the one described in the application could be used in order to embody the invention. For example, it does not seem conceivable to a person skilled in the art that exciting a substance using X-rays or a continuous current could produce the same effects or similar effects as exciting it by means of an HF electromagnetic field.

It was therefore decided not to examine Claims 3, 7, 11 and 15, nor Claims 8 to 10, 12 to 14 and 16 to 18 which are dependent on them.

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: III

4. Well-established laws of physics do not explain how, starting with an original substance, one might obtain a signal which, on being applied to a receiving substance, would enable the transmission of the properties of the original substance to that receiving substance, and moreover in a way which could be reproduced.

It is true that it is not always necessary to provide a theoretical explanation based on the established laws of physics in order to explain a novel result, provided that it is credible in the light of the application that the result observed by the applicant genuinely occurs, and that the invention defined in said application actually enables that result to be obtained.

However, in the present case the examples cited in the application do not prove convincingly that the two above-mentioned conditions have been met, for the following reasons: because, in the case of an invention which affects the fundamental principles of physics, experiments should have been performed in a completely independent laboratory (or in several) (after publication of the application, or possibly before, with said laboratory of course being constrained not to disclose the invention); and because it is not always clear how many times the experiments described in the application were performed, so that doubts remain as to whether they can be reproduced.

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: III

Everything seems at present to indicate to a person skilled in the art that the result sought by the applicant cannot be achieved, the signal obtained without an excitation field or after interaction with the excitation field being in fact merely an electrical signal "characteristic" of the original substance, that is "characteristic" in its everyday meaning. Consequently, there is a serious lack of clarity in the description and the claims, contrary to the requirements of PCT Article 5. Therefore, in accordance with the PCT Guidelines (PCT/GL/3, Chapter IV, point 4) it has been decided not to attribute novelty, inventive step or industrial applicability to the subject matter of new Claims 1 to 26.

VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

1. It is not clear in the table on page 22 how the readings that were used in calculating the averages indicated were obtained. Two interpretations are conceivable: either only twelve solutions, corresponding to four different concentrations of Ca++, were prepared and measurements taken for each of these solutions at different times; or the experiment was repeated several times, four fresh solutions being prepared each time for each signal being tested. It is not known at the present time which of these alternatives applies. Moreover, it is inexplicable that more measurements appear to have been taken for the samples subjected to the heparin signal than for the samples which were not subjected to any signal at all. A rigorously scientific procedure would have involved making the same number of measurements so that an **objective** comparison of the results could be made. Finally, these results do not seem to be truly significant, both in view of the standard deviations calculated and in view of the minimal difference in coagulation measured for solutions 1 and 4, which were subjected to the heparin signal or not subjected to any signal at all.

2. It is not understood why coagulation was assessed on the basis of criteria apparently lacking in precision (see the description of the application, page 21, lines 3 to 7), whereas instruments exist which can measure the coagulation of a solution precisely, by determining the degree of its

VII. Certain defects in the international application

cloudiness. The use of fuzzy criteria in defining this coagulation makes the result obtained unreliable, as the values measured depend too much on the experimenter's judgement.

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

1. It is doubtful that a substance emits an electromagnetic field particular to itself without having been excited in any way. The signal received by the system according to Claim 6 must in fact be caused merely by thermal noise, which would imply that the method and the system according to the invention do not enable reproducible results to be obtained.

2. Putting the feature claims between parentheses is not clear (PCT Article 6), as one does not know whether these features are to be taken into account or not when delimiting the extent of the claims.